DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-08

December 2, 1996

David M. Spirko, Owner
Laser Labs
5420 Pine Bay Drive
Tampa, Florida 33625

Dear Mr. Spirko:

During an inspection of your firm located at 6001 Johns Road #2-21, Tampa, Florida on November 19, 1996 FDA Investigators R. Kevin Vogel and Dennis R. Butcher determined that you refurbish (manufacture) various medical laser systems which are devices as defined by Section 201 (h) of the Federal Food, drug, and Cosmetic Act (the Act).

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to the following:

1) Lack of documentation of testing/inspection of finished laser systems to assure they meet the original manufacturer's specifications [21 CFR 820.160].

2) Lack of written specifications for incoming components and lack of documentation that incoming components meet required specifications [21 CFR 820.80 (a)].

3) Lack of ESD (Electrostatic Discharge) reduction procedures [21 CFR 820.46].

In addition, the devices are misbranded within the meaning of section 502(o) of the Act, in that they are being processed in an establishment not duly registered under Section 510 of the Act, and within the meaning of section 502(t)(2) in that you have failed to

furnish any material or information required by or under section 519 respecting the device. You failed to have in place and to apply written procedures to document events required to be reported under the Medical Device Reporting regulations.

This letter is not intended to be an inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including (1) the timeframes within which the corrections will be completed, and (2) any documentation indicating the correction has been achieved and an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

The Division of Small Manufacturers Assistance (DSMA) is available to assist you and can be contacted at 1350 Piccard Dr., Rockville, Maryland 20850 or at 1-800-638-2041, if you require additional help or copies of FDA guidance publications. We also encourage you to attend the upcoming FDA Workshop for Medical Devices in Orlando, Florida sponsored jointly by FDA, HIMA, and the Biomedical Manufacturers Association on January 14, 1997. A copy of the workshop agenda and registration form is enclosed for your information and use.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Florida District, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, ext. #264.

Sincerely,

Douglas D. Tolen
Director, Florida District

Enclosures